

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

IN RE: COLUMBIA UNIVERSITY
PATENT LITIGATION

MDL NO. 1592

IMMUNEX CORPORATION, a Washington
Corporation and AMGEN INC., a Delaware
Corporation,Civil Action No. 04-10740-MLW
C. D. Cal. No. CV 03-4349 MRP (CWx)

Plaintiffs,

vs.

THE TRUSTEES OF COLUMBIA
UNIVERSITY in the City of New York,
a New York Corporation,

Defendant.

AND RELATED COUNTERCLAIM

**AMGEN INC.'S AND IMMUNEX CORPORATION'S OPPOSITION
TO COLUMBIA UNIVERSITY'S MOTION TO RESTRICT
ACCESS TO THE '159 APPLICATION FILE**

Amgen opposes Columbia's request to restrict access to U.S. Patent Application No. 08/477,159 (the "'159 application"). Amgen demonstrates below that Columbia's request is rendered moot by previous disclosures of the '159 application to persons other than outside counsel. Although the Court requested briefing from Columbia on this issue, Amgen is filing this opposition to bring important facts to the Court's attention, which facts Columbia failed to disclose in its opening brief and Supplemental Submission.¹

Columbia's sudden confidentiality claim for the '159 application came as a surprise to Amgen and Immunex. Columbia's confidentiality claim flatly contradicts Columbia's past confidentiality position on the '159 prosecution file. In two separate instances, Columbia

¹ Amgen and Immunex vehemently deny Columbia's baseless accusation that they have violated ethical obligations by obtaining the '159 prosecution from the PTO. It is surprising that Columbia, whose counsel represented Amgen when this case was filed, is so carefree in charging an ethical violation.

conceded the non-confidentiality of portions of the '159 prosecution file, thereby waiving any claim of confidentiality. *See Ares-Serono, Inc. v. Organon Int'l B.V.*, 160 F.R.D. 1 (D. Mass. 1994) (ordering production of patent application filed in the Netherlands where confidentiality waived when party seeking discovery was previously permitted to inspect the application).

The first instance occurred in May 2002, when John White, Columbia's patent attorney, in its patent-misuse attempt to collect royalties based upon pending patent applications, disclosed the pending '159 claims to Immunex and represented that "copies of pending claims which we had sent to you on May 6, 2002 are not being treated as confidential with respect to licensees such as Immunex." White letters of May 6 and 15, 2002, letters attached as Ex. A and B, respectively (emphasis added).

The second instance occurred on July 15, 2003. On that date, Biogen and Genzyme filed their complaint and alleged inequitable conduct based upon Columbia's actions during the prosecution of the '159 application. Biogen and Genzyme Complaint at ¶¶ 61-65. Those allegations publicly described pending claims, the Patent Office response to those claims and Columbia's resulting cancellation of those claims. *See id.* at ¶ 62-64. Columbia never objected to this public disclosure of the '159 prosecution. Instead, when it answered the complaint, Columbia responded to those allegations by stating that "the '159 Application and its prosecution history speak for themselves." Columbia's Answer to Biogen and Genzyme Amended Complaint at ¶¶ 63-64. Other plaintiffs, including Amgen and Immunex, made similar allegations of inequitable conduct. Amgen and Immunex First Amended Complaint, filed September 24, 2003 at ¶¶ 45-49; *see also* Johnson & Johnson Complaint, filed November 6, 2003 at ¶¶ 57-61; Wyeth and Genetics Institute Complaint filed August 20, 2003 at ¶¶ 49-53; and Baxter Complaint filed November 12, 2003 at ¶¶ 58-62. In response to Amgen's and

Immunex's complaint, after several dilatory motions, Columbia similarly responded by stating that "the '159 application speaks for itself." Columbia's Answer to Amgen and Immunex First Amended Complaint at ¶¶ 45-49; *see also* Columbia's Answer to Johnson & Johnson Complaint at ¶¶ 57-60; Columbia's Answer to Wyeth and Genetics Institute Complaint at ¶¶ 49-52; Columbia's Answer to Baxter Complaint at ¶¶ 58-61. Columbia's prior conduct condoning the non-confidentiality of the '159 application should preclude it from restricting access here.

In addition, no policy reason exists for restricting access to the '159 application. The evident purpose of the confidentiality proviso of 35 U.S.C. § 122 is to preserve any trade secret or other confidential information of the applicant if and until the application issues as a patent. *Lee Pharms. v. Kreps, Secretary of Commerce*, 198 U.S.P.Q. 601, 608 (9th Cir. 1978) (The "purpose of the confidentiality proviso is to prevent the patent laws from being frustrated by permitting inventors' discoveries to become public knowledge before a patent is secured."); *In re Mosher*, 199 U.S.P.Q. 82, 84 (C.C.P.A. 1978). The technical disclosure of Columbia's '159 application published in 1983 when the first patent claiming priority to that application issued. The only information to be gained from access to the '159 prosecution is Columbia's prolonged negotiations with the Patent Office in an attempt to draft a claim that can avoid a double patenting rejection over its expired patents claiming priority to the same disclosure. "Nor should the rules of Practice of the Patent Office be used to preclude the Court from having the benefit of all relevant evidence in order to reach the truth." *Crown Machine & Tool Co. v. Sutherland Paper Co.*, 244 F. Supp. 543, 544 (N.D. Ca. 1965); *James B. Clow & Sons, Inc. v. United States Pipe and Foundry Co.*, 313 F.2d 46, 51 (5th Cir. 1963).

In fact, Columbia admitted the importance of plaintiffs' access to pending applications. In its Motion to Stay, Columbia relied upon the fact that the plaintiffs will have access to

Columbia's reexamination and promised reissue prosecution. Columbia's Memo in Support of Motion to Stay at 13-14.² There is no reason to treat the prosecution of the '159 application, which contains nearly identical claims and relies upon the same specification as the '275 patent, any differently than the reexamination -- particularly now that it has been publicly disclosed with no objection by Columbia.

If the Court grants Columbia's request to restrict access to the '159 application, which Amgen and Immunex oppose, in-house counsel access should not be restricted. Amgen and Immunex in-house counsel are integral and critical members of the litigation team. Columbia voluntarily disclosed the '159 claims to Immunex in-house counsel. Columbia provides no justification for its about face on access to in-house counsel because it cannot.

Dated: June 18, 2004

Respectfully submitted,

IMMUNEX CORPORATION and AMGEN INC.
By their attorneys,

/s/ Eileen M. Herlihy
Eileen M. Herlihy (BBO #231410)
PALMER & DODGE LLP
111 Huntington Avenue at Prudential Center
Boston, MA 02199-7613
Telephone: (617) 239-0100
Facsimile: (617) 227-4400

² Columbia further stated that during reexamination, it "intends to disclose to the PTO the references that plaintiffs contend should have been disclosed." *Id.* at 12. Because rejections of claims prosecuted in the related '159 prosecution history are among the references that plaintiffs contend should have been disclosed, Columbia will be further disclosing the '159 application and its file during reexamination of the '275 patent. See 37 C.F.R. § 1.98(a)(2)(iii)-(iv) (providing that an Information Disclosure Statement citing an application should include "the application specification including the claims, . . . or that portion of the application which caused it to be listed including any claims directed to that portion; and . . . all other information or that portion which caused it to be listed.").

Arthur Wineburg (DC #163220)
PILLSBURY WINTHROP LLP
1133 Connecticut Avenue, NW
Washington, DC 20036-4305
Telephone: (202) 775-9800
Facsimile: (202) 833-8491

Vicki G. Norton (CA #175067)
WILSON SONSINI GOODRICH & ROSATI
3611 Valley Centre Drive, Suite 525
San Diego, CA 92130
Telephone: (858) 350-2300
Facsimile: (858) 350-2399

Kirke M. Hasson (CA #61446)
PILLSBURY WINTHROP LLP
50 Fremont Street
San Francisco, CA 94105-2228
Telephone: (415) 983-1000
Facsimile: (415) 983-1200

SERVICE LIST FOR AMGEN FILING

I hereby certify that a copy of the foregoing Amgen Inc.'s and Immunex Corporation's Opposition to Columbia University's Motion to Restrict Access of the '159 Application File has been served by mail on this 18th day of June, 2004.

BAXTER HEALTHCARE CORPORATION v. THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

Counsel for Plaintiff Baxter Healthcare Corporation

Donald R. Ware
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02210-2600
Office: (617) 832-1000
Fax: (617) 832-7000

BIOGEN, INC., GENZYME CORPORATION and ABBOTT BIORESEARCH CENTER, INC. v. THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

Counsel for Plaintiffs Biogen, Inc. and Genzyme Corp.

Donald R. Ware
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02210-2600
Office: (617) 832-1000
Fax: (617) 832-7000

Counsel for Plaintiff Abbott Bioresearch Center, Inc.

Mark A. Pals
KIRKLAND & ELLIS LLP
AON Building
200 East Randolph Drive
Suite 5400
Chicago, IL 60601
Office: (312) 861-2000
Fax: (312) 861-2200

GENENTECH, INC. v. THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

Counsel for Plaintiff Genentech, Inc.

Victoria F. Maroulis
QUINN EMANUEL URQUHART OLIVER & HEDGES, LLP
555 Twin Dolphin Drive, Suite 560
Redwood Shores, California 94065
Office: (650) 620-4500
Fax: (650) 620-4555

IMMUNEX CORPORATION AND AMGEN INC v. THE TRUSTEES OF COLUMBIA UNIVERSITY

Counsel for The Trustees of Columbia University in the City of New York

Kevin S. Rosen
GIBSON, DUNN & CRUTCHER, LLP
2029 Century Park East, Suite 4000
Los Angeles, California 90067-4276
Office: (310) 552-8500
Fax: (310) 557-8741

JOHNSON & JOHNSON v. THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

Counsel for Plaintiff Johnson & Johnson

Steven A. Zalesin
PATTERSON, BELKNAP, WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036
Office: (212) 336-2000
Fax: (212) 336-2222

THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK v. JOHNSON & JOHNSON

Counsel for Defendant Johnson & Johnson

Steven A. Zalesin
PATTERSON, BELKNAP, WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036
Office: (212) 336-2000
Fax: (212) 336-2222

WYETH AND GENETICS INSTITUTE LLC v. THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

Counsel for Plaintiffs Wyeth and Genetics Institute LLC

Leora Ben-Ami
KAYE SCHOLER, LLP
425 Park Avenue
New York, NY 10022-7203
Office: (212) 836-8000
Fax: (212) 836-8689

and

Counsel for The Trustees of Columbia University in the City of New York

David I. Gindler
IRELL & MANELLA LLP
1800 Avenue of the Stars
Suite 900
Los Angeles, CA 90067-4276
Office: (310) 277-1010
Fax: (310) 203-7199

Wayne Barsky
GIBSON DUNN & CRUTCHER LLP
333 South Grand Avenue
Los Angeles, CA 90071-3197
Office: (213) 229-7000
Fax: (213) 229-7520

EXHIBIT A

COOPER & DUNHAM LLP
ATTORNEYS AT LAW
1185 AVENUE OF THE AMERICAS, NEW YORK, NEW YORK 10036
TELEPHONE: (212) 570-0460

COOPER & DUNHAM
ATTORNEYS AT LAW
1185 AVENUE OF THE AMERICAS
NEW YORK, NEW YORK 10036
TELEPHONE: (212) 570-0460
FACSIMILE: (212) 570-0625
(212) 570-0636
(212) 570-0630

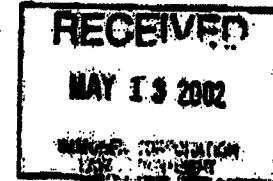
COOPER & DUNHAM
ATTORNEYS AT LAW
1185 AVENUE OF THE AMERICAS
NEW YORK, NEW YORK 10036
TELEPHONE: (212) 570-0460
FACSIMILE: (212) 570-0625
(212) 570-0636
(212) 570-0630

FACSIMILE: (212) 570-0625
(212) 570-0636
(212) 570-0630

May 6, 2002

* New York Office and Associate Practice

Vasant Gandhi, J.D., Ph.D.
Senior Counsel
Immunex Corporation
51 University Street
Seattle, WA 98101-2936



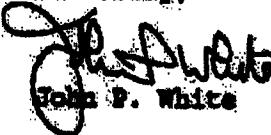
Re: License Under Axal Patents

Dear Dr. Gandhi:

At the request of Scot G. Hamilton of Columbia University I enclose copies of the claims in the two pending applications included with the Licensed Patent Rights.

Please contact Mr. Hamilton or me if you have further questions.

Sincerely,


John P. White

JPW/Zip
Enclosures

cc: Scot G. Hamilton, Esq. (w/o enclosures)
Susan L. Sgarlat, Esq. (w/o enclosures)

EXHIBIT B

COOPER & DUNHAM LLP
ATTORNEYS AT LAW
1185 AVENUE OF THE AMERICAS, NEW YORK, NEW YORK 10036
TELEPHONE: (212) 576-9400

CHRISTOPHER G. BURGAN
NORMAN H. BYRN
JOHN P. WHITE
WILLIAM E. PECTON
ROBERT E. KATE
PETER J. PHILLIPS
ROBERT L. MILLER
ROBERT T. MALLONAGA
EDWARD J. KIRKLAND
PETER C. FERNANDEZ
JAMES H. LOVE
MICHAEL F. MCGINN
RICHARD A. BERNSTEIN
FRANK A. BROWN
CHRISTOPHER H. KIM
STEPHEN G. LEVINSKY
MARIA G. MARRAS

PAUL B. CALVETTE
PETER B. GALTREY
JAY H. HADLEY
ROBERT B. HORNSTEIN
MICHAEL B. KERKOFF
ROBERT A. LEWIN
ROTHAINE L. MILLER
MICHAEL K. MONTAGUE
PAUL TIGHE
DAVID J. WILKINS
THOMAS W. YOUNG
STEPHEN M. ZABRISKIE
ALAN B. ZELLER
CHRISTOPHER B. WILSON
JAMES B. MARSH
ROTH L. KARNAK

* NEW YORK STATE BAR ATTORNEY
** ADMITTED IN MASSACHUSETTS ONLY

FACSIMILE: (212) 576-0525
(212) 576-0526
(212) 576-0530

OF COUNSEL:
JOHN B. KARBER
ALAN J. MORRISON

DISPUTED ATTORNEYS:
CHRISTOPHER H. KIRKLAND
ROBERT T. MALLONAGA

PATENT ATTORNEYS:
CHRISTOPHER H. KIRKLAND
ROBERT T. MALLONAGA

TRADEMARK ATTORNEY:
CHRISTOPHER H. KIRKLAND

May 15, 2002

(NY FACSIMILE)

Vasant Gandhi, J.D., Ph.D.
Senior Counsel
Immunex Corporation
51 University Street
Seattle, WA 98101-2936

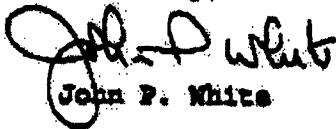
Re: License Under Axal Patents

Dear Dr. Gandhi:

This letter is sent to confirm our May 15, 2002 telephone call during which I indicated to you that copies of pending claims which we had sent to you on May 6, 2002 are not being treated as confidential with respect to licensees such as Immunex.

Please contact me if you have any further questions.

Sincerely,


John P. White

JPW/far
Enclosures

cc: Scott G. Hamilton, Esq.
Susan L. Sgarlat, Esq.